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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,925	09/21/2001	Hideaki Yagi	Q66253	2471

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EXAMINER

KOKABI, AZADEH

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/956,925	Applicant(s) YAGI ET AL.	
	Examiner Azy Kokabi	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4,-10, 12, 14-22, 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11,13 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4,-10, 12, 14-22, 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-8, 15, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobatake et al (U.S. Patent No. 5,720,276).

Kobatake et al disclose an oxygen enriching device that supplies oxygen gas to a user synchronously with the exhalation and inhalation of the user. The apparatus includes an oxygen outlet in the form of outlet port (12p) that supplies oxygen-enriched gas to the user.

The device of Kobatake includes a controller (#22) and pressure sensor (#34). The pressure sensor (#34) is disposed on a flow passage (#18) that reaches a breath detection port in the nasal cannulae (#36). During an intermittent mode, the controller (#22) interacts with the sensor (#34) and a valve (#32) to control the flow of oxygen. The state of inhalation or expiration is detected based on a signal from the sensor (#34 and see, e.g. column 7, lines 7-29).

The controller disclosed for performing the operations recited in claim 1 includes a recording medium in the form of RAM (#22a) and/or ROM (#22b). The main passage (#18a) of the device includes a control member that adjusts the opening in the main passage (#18a) in the form of an adjustable flow reducer (#24). A bypass flow passage (#18b) bypasses the control member (#24). The bypass flow passage further includes flow rate adjuster (#26, see figure 1).

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The oxygen enriching device disclosed by Kobatake et al further includes a tank (#12h) in an oxygen-enriched gas supply passage and downstream of an oxygen enriching section that includes a compressor (#12a) and nitrogen absorber (#12f, see also figure 1 and 2).

The apparatus disclosed by Kobatake et al includes a switch (#40) that allows the device to provide either a continuous flow of oxygen to a patient or a pulsed flow wherein the pulsed flow is delivered during a time that corresponds to 25-40% of the breath cycle, namely one-third of the mean time for the respiration (see the third full paragraph in column 7).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 9-10, 12, 14, 16, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobatake in view of Hete et al (U.S. Patent No. 6,123,074).

As previously, discussed in paragraph 2 above, Kobatake et al disclose all the limitations as set forth, however Kobatake fails to disclose a means for controlling the oxygen enriched gas

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at a first flow rate during the inhalation period and at a second flow rate during the exhalation period and a third flow rate during breath synchronization.

Hete et al teaches means for providing oxygen-enriched gas at a flow rate above the average continuous flow rate during inhalation and decreasing the flow of gas below the average flow rate to the patient during exhalation (see column 8, line 66 through column 9, line 27).

At the time of invention, it would have been obvious to one of ordinary skill in the art to modify the oxygen enriching apparatus disclosed by Kobatake et al to configure the disclosed means for controlling gas flow to the user to provide oxygen-enriched gas at a first, second, and third flow rates corresponding to the IPAP, EPAP, and average continuous flow rates taught by Hete et al. One would have been motivated to make such a modification in order to make the user more comfortable, which is well-know benefit of bi-level positive pressure ventilators (see at least column 4, lines 17-21 of US patent No. 5,148,802 to Sanders et al).

6. Claims 17, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobatake et al in view of Davenport (U.S. Patent No. 6,237,594).

As previously, disclosed in paragraph 2 above, Kobatake et al disclose all the limitations as set forth, however Kobatake fails to disclose a plurality of tanks in series in the oxygen-enriched gas supply passage.

However, the use of a plurality of tanks in an oxygen supply passage was known at the time of invention. For example, Davenport discloses an oxygen supply device wherein a number of tanks (i.e., boluses 46 and 50) are used to allow the device to deliver a broad range of flow to the patient without negatively impacting the performance of the valves and sensors. A check valve (#62) is provided between the boluses (see column 5, lines 60-68).

Accordingly, it would have been obvious to one with ordinary skill in the art to have modified the device of Kobatake to include additional tanks in the gas supply lines, as taught by Davenport, in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

Regarding the size of the tanks as recited in claim 19, although the size of the tanks/boluses is not expressly disclosed, it is well known that the greater the size of the buffer tanks, the greater the efficiency in delivering gas to a patient over a wide range of flow rates (See, e.g., the discussion of Table 4 of U.S. Patent No. 4,681,009 to Sato et al). Accordingly, because the applicants does not disclose the tank sized at 500mL or more solves a problem or provides an advantages not addressed in the prior art, it would have been an obvious design choice to provide tanks having at least 500mL capacity in order to efficiently provide the range of desired flow rates.

7. Claims 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobatake in view of Hete as applied to claim 9 above, and further in view of Davenport (U.S. Patent No. 6,237,594).

Kobatake et al in view of Hete et al teach the invention recited in claims 18, 20, and 22 except for the use of a plurality of tanks in the gas supplying line.

However, the use of a plurality of tanks in an oxygen supply passage was known at the time of invention. For example, Davenport discloses an oxygen supply device wherein a number of tanks (i.e., boluses 46 and 50) are used to allow the device to deliver a broad range of flow to the patient without negatively impacting the performance of the valves and sensors. A check valve (#62) is provided between the boluses (see column 5, lines 60-68).

Accordingly, it would have been obvious to one with ordinary skill in the art to have modified the device of Kobatake to include additional tanks in the gas supply lines, as taught by Davenport, in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

Regarding the size of the tanks as recited in claim 18, although the size of the tanks/boluses is not expressly disclosed, it is well known that the greater the size of the buffer tanks, the greater the efficiency in delivering gas to a patient over a wide range of flow rates (See, e.g., the discussion of Table 4 of U.S. Patent No. 4,681,009 to Sato et al). Accordingly, because the applicants does not disclose the tank sized at 500mL or more solves a problem or provides an advantages not addressed in the prior art, it would have been an obvious design choice to provide tanks having at least 500mL capacity in order to efficiently provide the range of desired flow rates.

8. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobatake et al in view of Frye et al (U.S. Patent No. 6,394,008).

As previously, stated in paragraph 2 above, Kobatake discloses all the limitations as set forth, however Kobatake fails to disclose a breath detection port that is provided separately from the oxygen outlet, and in which the oxygen-enriched gas is not supplied to the breath detection port.

Frye et al discloses an oxygen delivery system having an oxygen outlet (#34) and a separate breath detection port (#36). The breath detection port conveys and transmits the pressure conditions induced during the patient's breathing (see at least column 8, lines 34-52). The breath detection port is provided separately from the oxygen outlet to help retain a sensing

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diaphragm in a closed position in response to a lack of inhalation by a patient during exhalation.
(see at least column 10, lines 15-40).

In view of Frye, it would have been obvious to one of ordinary skill in the art to have provided for a breath detection port, which is separate from the oxygen outlet, as taught by Frye, in order to control the amount of oxygen a patient receives during inhalation and exhalation.

9. Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobatake et al in view of Hete et al (U.S. Patent No. 6,123,074) in further view of Frye et al (U.S. Patent No. 6,394,008).

As previously, stated in paragraph 5 above, Kobatake and Hete disclose all the limitations as set forth, however Kobatake fails to disclose a breath detection port that is provided separately from the oxygen outlet, and in which the oxygen-enriched gas is not supplied to the breath detection port.

Frye et al discloses an oxygen delivery system having an oxygen outlet (#34) and a separate breath detection port (#36). The breath detection port conveys and transmits the pressure conditions induced during the patient's breathing (see at least column 8, lines 34-52). The breath detection port is provided separately from the oxygen outlet to help retain a sensing diaphragm in a closed position in response to a lack of inhalation by a patient during exhalation.
(see at least column 10, lines 15-40).

In view of Frye, it would have been obvious to one of ordinary skill in the art to have provided for a breath detection port, which is separate from the oxygen outlet, as taught by Frye, in order to control the amount of oxygen a patient receives during inhalation and exhalation.

Response to Arguments

10. Applicant's arguments filed 12/04/07 have been fully considered but they are not persuasive. Applicant argues that Kobatake et al fails to disclose a breath detection port that is separate from the oxygen outlet. Applicant states on page 12 of the remarks and argument filed on 12/04/03 that "claim 1 adequately recites that the oxygen enriching apparatus has each of an oxygen outlet and a breath detection port connected to the inhalator." However, this claim limitation does not read upon a device having a separate oxygen outlet and breath detection port. The device of Kobatake has an oxygen outlet (#12p) and a breath detection port, which are connected to the nasal cannulae (#36). Applicant would have examiner read the limitation of the specification into the broad claim language.

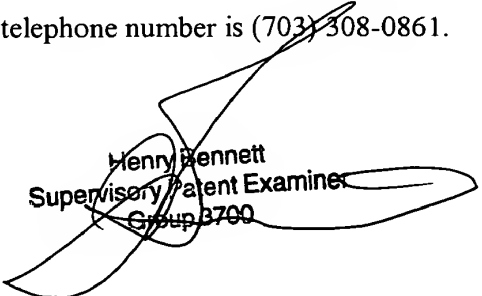
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

AK 


Henry Bennett
Supervisory Patent Examiner
Group 3700